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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,055	08/08/2001	Wayne R. Kindsvogel	00-56	2607

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ZymoGenetics, Inc.  
1201 Eastlake Avenue East  
Seattle, WA 98102

EXAMINER

ANDRES, JANET L

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 11/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

09/925,055

### Applicant(s)

KINDSVOGEL ET AL.

### Examiner

Janet L. Andres

### Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 43 and 46-69 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 43 is/are allowed.
- 6) ☒ Claim(s) 46-67 is/are rejected.
- 7) ☒ Claim(s) 68,69 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **RESPONSE TO AMENDMENT**

1. Applicant's amendment filed 7 September 2004 is acknowledged. Claims 43 and 46-69 are pending and under examination in this office action. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

#### ***Claim Rejections Withdrawn***

2. The rejection of claims 51-53 under 35 U.S.C. 112, first paragraph, as lacking written description is withdrawn in response to Applicant's amendment and arguments.

3. The rejection of claims 43-45 under 35 U.S.C. 112, first paragraph, as lacking enablement is withdrawn in response to Applicant's cancellation of these claim 44 and 45 and arguments with respect to claim 43.

#### ***Claim Rejections Maintained***

4. The rejection of claims 61-66 under 35 U.S.C. 102(a) and (e) as anticipated by the '704 patent and under 102(b) as anticipated by WO 99/07848 are maintained for reasons of record in the office action of 4 March 2004 and applied to new claim 67.

As Applicant states, the disclosures of the "704 patent and of WO 99/07848 are identical. Applicant's arguments are thus addressed as they apply to both rejections. Applicant has amended the claims to require complexes between SEQ ID NO: 3 and other receptors. Applicant argues that not every element of the claims are included in the '704 patent because the '704 patent does not teach anything about the association of zcytor11 to any ligand. Thus, Applicant argues, the claim limitations of binding or antagonizing IL-TIF are not taught. Applicant additionally argues that the limitations of homodimeric, heterodimeric, or multimeric receptors are not necessarily present.

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Applicant's arguments have been fully considered but have not been found to be persuasive.

As the '704 patent teaches in column 5, lines 8-19, zcytor11 is a class II cytokine receptor. Thus homodimers of zcytor11 meet the limitations of claims 61-67 as amended. The '704 patent also teaches complexes with other type I and type II receptors, including interferon receptors, in column 11, lines 38-45. Thus Applicant's amendment fails to overcome the rejection.

In answer to Applicant's arguments with respect to inherency, a composition with the same physical properties as that claimed by Applicant would form multimers and would bind and antagonize IL-TIF. See MPEP §2112.01:

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433. See also Titanium Metals Corp. v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985)

In the instant case, the sequences of two products are the same. Thus, they would do the same things. If the product claimed instantly can form a dimer or multimer, the product in the art can do the same. Such dimerization or multimerization would occur when then protein was in solution, regardless of whether that fact was realized at the time or not. However, the '704 patent in fact specifically recognizes this inherent characteristic of cytokine receptors in column 4, lines 34-43 and specifically teaches interaction with other receptors in column 11, lines 38-45,

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as stated above. The '704 patent does not teach that the protein of the art would also bind and antagonize IL-TIF. However, for the reasons set forth above, it need not do so for Applicant's claims to be anticipated. Applicant has provided no evidence as to why two proteins with identical sequences would not possess the same characteristics. The discovery of a previously unrecognized characteristic does not render the product itself novel.

5. The rejection of claims 46-60 under 35 U.S.C. 112, first paragraph, as lacking enablement is maintained for reasons of record in the office action of 4 March 2004.

Applicant argues that it has been demonstrated that IL-TIF induces inflammation, and that it enhances inflammation and inflammatory response. Applicant argues that use of soluble zcytor11 receptors to inhibit IL-TIF is documented throughout the specification, and that diseases which would benefit from suppression or reduction of IL-TIF are provided.

Applicant's arguments have been fully considered but have not been found to be persuasive. What the specification teaches is that IL-TIF is "suspected to be involved in promoting TH1-type immune responses" and that "it is induced by a factor that is "implicated in asthma, lung mastocytosis, and other diseases" (p. 12, lines 23-29). Applicant lists a number of diseases (p. 13, lines 18-30) that might be treatable by zcytor11. Example 13 provides evidence that exogenously administered IL-TIF causes an inflammatory response and suggests that this might implicate IL-TIF in various inflammatory diseases. However, the fact that IL-TIF, when administered, causes an inflammatory response does not provide any guidance as to what diseases actually result in its expression, and thus what diseases can actually be treated by inhibiting it. For inhibition of IL-TIF to be useful, it must first be present. That administering it causes a particular response does not serve to indicate that if the response is observed, IL-TIF is

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responsible. There are many molecules that are capable of producing an inflammatory response. There is no guidance provided by the specification to indicate that IL-TIF is in fact present in such diseases as Crohn's disease, diabetes, pancreatic cancer, sepsis, asthma, end-stage renal disease, psoriasis, Grave's disease, colon cancer, or other disease that the specification suggests zcytor11 could be used to treat. What is provided is thus the idea for an invention, and the invitation to experiment to implement this invention, not the invention itself.

***Allowable Subject Matter***

6. Claims 69 and 69 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

CLAIM 43 IS ALLOWED. CLAIMS 68 AND 69 ARE OBJECTED TO. CLAIMS 46-67 ARE REJECTED.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Andres whose telephone number is 571-272-0867. The examiner can normally be reached on Monday, Tuesday, Thursday, Friday, 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Andres, Ph.D.  
23 November 2004

  
JANET ANDRES  
PRIMARY EXAMINER